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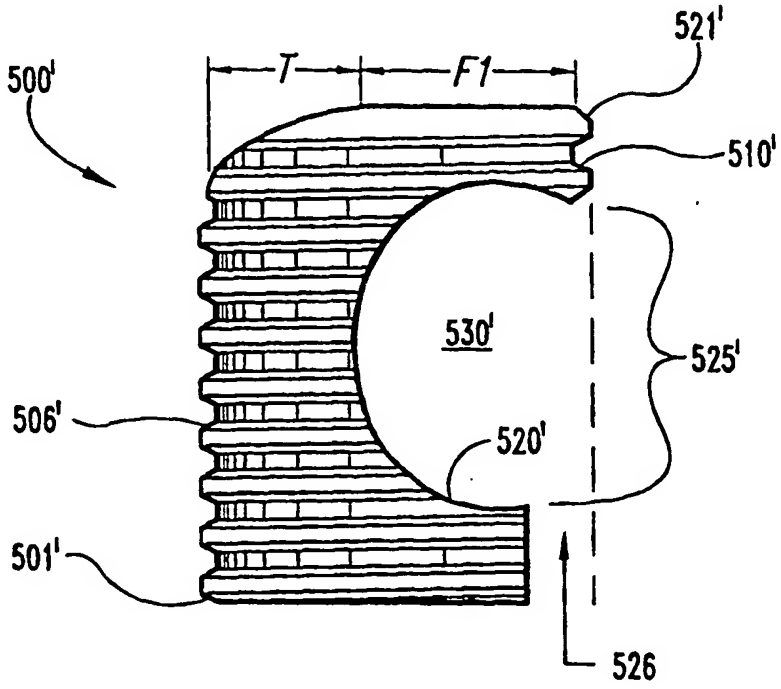
(54) Title: OPEN INTERVERTEBRAL SPACER

(57) Abstract

Open chambered spacers, implanting tools and methods are provided. The spacers (500') include a body (505') having a wall (506') which defines a chamber (530') and an opening (531') in communication with the chamber (530'). In one embodiment the wall (506') includes a pair of arms (520', 521') facing one another and forming a mouth (525') to the chamber (530'). Preferably, one of the arms (520') is truncated relative to the other, forming a channel (526). In one aspect the body (505') is a bone dowel comprising an off-center plug from the diaphysis of a long bone. The tools (800) include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In some embodiments, the occlusion means (820) includes a plate (821) extendable from the housing (805). In one specific embodiment the plate (821) defines a groove (822) which is disposed around a fastener (830) attached to the housing (805) so that the plate (821) is slideable relative to the housing (805).



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OPEN INTERVERTEBRAL SPACER

FIELD OF THE INVENTION

The present invention broadly concerns arthrodesis for stabilizing the spine. More specifically, the invention provides open-chambered intervertebral spacers, instruments for implanting the spacers and methods for making and using the spacers.

BACKGROUND OF THE INVENTION

Intervertebral discs, located between the endplates of adjacent vertebrae, stabilize the spine, distribute forces between vertebrae and cushion vertebral bodies. A normal intervertebral disc includes a semi-gelatinous component, the nucleus pulposus, which is surrounded and confined by an outer, fibrous ring called the annulus fibrosus. In a healthy, undamaged spine, the annulus fibrosus prevents the nucleus pulposus from protruding outside the disc space.

Spinal discs may be displaced or damaged due to trauma, disease or aging. Disruption of the annulus fibrosus allows the nucleus pulposus to protrude into the vertebral canal, a condition commonly referred to as a herniated or ruptured disc. The extruded nucleus pulposus may press on a spinal nerve, which may result in nerve damage, pain, numbness, muscle weakness and paralysis. Intervertebral discs may also deteriorate due to the normal aging process or disease. As a disc dehydrates and hardens, the disc space height will be reduced leading to instability of the spine, decreased mobility and pain.

Sometimes the only relief from the symptoms of these conditions is a discectomy, or surgical removal of a portion or all of an intervertebral disc followed by fusion of the

adjacent vertebrae. The removal of the damaged or unhealthy disc will allow the disc space to collapse. Collapse of the disc space can cause instability of the spine, abnormal joint mechanics, premature development of arthritis or nerve damage, in addition to severe pain. Pain relief via discectomy and arthrodesis requires preservation of the disc space and eventual fusion of the affected motion segments.

Bone grafts are often used to fill the intervertebral space to prevent disc space collapse and promote fusion of the adjacent vertebrae across the disc space. In early techniques, bone material was simply disposed between the adjacent vertebrae, typically at the posterior aspect of the vertebra, and the spinal column was stabilized by way of a plate or rod spanning the affected vertebrae. Once fusion occurred, the hardware used to maintain the stability of the segment became superfluous and was a permanent foreign body. Moreover, the surgical procedures necessary to implant a rod or plate to stabilize the level during fusion were frequently lengthy and involved.

It was therefore determined that a more optimal solution to the stabilization of an excised disc space is to fuse the vertebrae between their respective end plates, preferably without the need for anterior or posterior plating. There have been an extensive number of attempts to develop an acceptable intradiscal implant that could be used to replace a damaged disc and maintain the stability of the disc interspace between the adjacent vertebrae, at least until complete arthrodesis is achieved. The implant must provide temporary support and allow bone ingrowth. Success of the discectomy and fusion procedure requires the development of a contiguous growth of bone to create a solid mass because the implant may not withstand the compressive loads on the spine for the life of the patient.

Several metal spacers have been developed to fill the void formed and to promote fusion. Sofamor Danek Group,

Inc., (1800 Pyramid Place, Memphis, TN 38132, (800) 933-2635) markets a number of hollow spinal cages. For example, U.S. Patent No. 5,015,247 to Michelson and U.S. Serial No. 08/411,017 to Zdeblick disclose a threaded spinal cage. The cages are hollow and can be filled with osteogenic material, such as autograft or allograft, prior to insertion into the intervertebral space. Apertures defined in the cage communicate with the hollow interior to provide a path for tissue growth between the vertebral endplates.

Although the metal fusion devices of Sofamor Danek and others are widely and successfully employed for reliable fusions, it is sometimes desirable to use an all-bone product. Bone provides many advantages for use in fusions. It can be incorporated after fusion occurs and therefore will not be a permanent implant. Bone allows excellent postoperative imaging because it does not cause scattering like metallic implants. Stress shielding is avoided because bone grafts have a similar modulus of elasticity as the surrounding bone. Although an all-bone spacer provides these and other benefits, the use of bone presents several challenges. Any spacer which will be placed within the intervertebral disc space must withstand the cyclic loads of the spine. Cortical bone products may have sufficient compressive strength for such use, however, cortical bone will not promote rapid fusion. Cancellous bone is more conducive to fusion but is not biomechanically sound as an intervertebral spacer.

Several bone dowel products such as the Cloward Dowel have been developed over the years. Bone dowels in the shape of a generally circular pin can be obtained by drilling an allogeneic or autogeneic plug from bone. As shown in Figures 1 and 2, the dowels 100, 200 have one or two cortical surfaces 110 and an open, latticed body of brittle cancellous bone 120, 220 backing the cortical

surface 210 or between the two cortical surfaces 110. The dowels 100, 200 also include a drilled and/or tapped instrument attachment hole 115, 215. Dowels and other bone products are available from the University of Florida Tissue Bank, Inc., (1 Innovation Drive, Alachua, Florida 32615, 904-462-3097 or 1-800-OAGRAFT; Product numbers 280012, 280014, and 280015).

While the bone dowels of the prior art are valuable bone grafting materials, these dowels have relatively poor biomechanical properties, in particular a low compressive strength. Accordingly, these dowels may not be suitable as an intervertebral spacer without internal fixation due to the risk of collapsing prior to fusion under the intense cyclic loads of the spine. A need remains for dowels having the advantages of allograft but with even greater biomechanical strength.

In response to this need, the University of Florida Tissue Bank, Inc., has developed a proprietary bone dowel machined from the diaphysis of long bones. Referring now to Figure 3, the dowel 300 includes a tool engagement end 301 and an opposite insertion end 302. Between the two ends 301 and 302, the dowel 300 includes a chamber 330 formed from the naturally occurring medullary canal of the long bone and an opening 331 in communication with the chamber 330. The chamber 330 can be packed with an osteogenic material to promote fusion while the cortical body 305 of the dowel 300 provides support. The dowels are also advantageous in that they provide desirable biomechanics and can be machined for various surface features such as threads or annular ribbing. In some embodiments, the outer cortical surface 310 of the tool engagement end 301 is machined with an instrument attachment feature and an alignment score mark. As shown in Figure 3, the insertion end 302 may include a chamfered portion 340.

While these diaphysial cortical dowels are a major advance in this field, a need has remained for bone dowels and other intervertebral spacers with greater versatility.

SUMMARY OF THE INVENTION

This invention provides spacers having an open chamber, tools for implanting the spacers and methods for making and using the spacers. The spacers include a body having a wall which defines a chamber and an opening in communication with the chamber. In one aspect, a channel is defined in the wall in communication with the chamber and the outer surface of the spacer. In another embodiment the wall includes a pair of arms facing one another and forming a mouth to the chamber. In a preferred embodiment, one of the arms is truncated relative to the other. In some aspects, the body is composed of bone. In one aspect the body is a dowel having a substantially C-shaped chamber and comprising an off-center bone plug obtained from the diaphysis of a long bone.

Tools for implanting spacers are also provided. The tools include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In one aspect the engaging means includes a shaft slidingly disposed within a housing and having a threaded post for engaging a threaded tool hole in the spacer. In some embodiments, the occlusion means includes a plate extendable from the housing. In one specific embodiment the plate defines a groove which is disposed around a fastener attached to the housing so that the plate is slideable relative to the housing.

This invention also includes methods for obtaining an open bone dowel and methods for using the spacers of this invention. The methods of making a dowel according to this invention include cutting an off-center plug from the diaphysis of a long bone to obtain a bone dowel having an open chamber. In one aspect, the dowel is machined to include desirable surface features such as threads, grooves

and instrument holes. In still another aspect, the methods include chamfering the forward end of the dowel. The methods for using the spacers of this invention include making a cavity between two vertebrae to be fused and implanting a spacer having an open chamber. In some embodiments the chamber is packed with osteogenic material before the spacer is implanted. In other aspects of the invention, osteogenic material is packed into and around the chamber through the mouth or channel after implantation.

The combination of the open-chambered spacers of this invention with the tools and methods of this invention provide a versatile spacer without any compromise in biomechanical integrity. The spacers can be packed before or after implantation. This invention facilitates implanting a pair of open spacers close to each other in an intervertebral space. Where the spacer is a bone dowel, the dowel can be formed with less bone than is needed for conventional dowels, conserving precious bone stock.

Accordingly, it is one object of this invention to provide an open-chambered fusion spacer and methods for using the spacer in an arthrodesis procedure.

Another object is to improve patient incidence of safe and satisfactory spinal stabilization and fusion.

Another object of this invention is to provide a dowel for vertebral fusions which has improved biomechanical properties and versatility over standard dowels known in the art.

Still another object of the present invention is to provide a spacer with satisfactory biomechanical features and improved osteogenic and fusion promoting features.

These and other objects, advantages and features are accomplished according to the spacers, tools and methods of the following description of the preferred embodiments of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a standard Cloward Dowel known in the art.

Figure 2 shows a standard unicortical dowel known in the art.

Figure 3 shows a diaphysial cortical dowel produced and sold by The University of Florida Tissue Bank, Inc.

Figure 4 is a side perspective view of one embodiment of the open-chambered spacer of this invention.

Figure 5 is an end elevational view of the spacer of Figure 4.

Figure 6 is a top elevational view of a pair of open chambered dowels of this invention implanted within an intervertebral space.

Figure 7 depicts the anatomy of a lumbar vertebral segment.

Figure 8 is a top elevational view of a pair of open chambered dowels of this invention implanted within an intervertebral space via an anterior surgical approach.

Figure 9 is a top elevational view of a pair of open chambered dowels of this invention implanted within an intervertebral space via a posterior surgical approach.

Figure 10 is a side perspective view of one embodiment of an open chambered dowel having a truncated arm defining a channel to the mouth and chamber.

Figure 11 is a top perspective view of an open chambered dowel with arms defining concave faces.

Figure 12 is a top perspective view of an open chambered bone dowel.

Figure 13 is a side perspective view of one embodiment of this invention in which the dowel is grooved.

Figure 14 is a side perspective view of a threaded dowel of this invention.

Figure 15 is a side cross-sectional view of a detail of a portion of the threads of a spacer of this invention.

Figure 16 shows various cuts across bone diaphysis and the resulting dowels formed according to this invention..

Figure 17 is a top elevational view of one embodiment of a dowel threader of this invention.

Figure 18 is a side elevational view of the dowel threader of Figure 17.

Figure 19 is an end elevational view of the dowel threader of Figures 17 and 18 showing elements of the cutter assembly.

Figure 20 is a detailed view of a single tooth of one cutter blade of the dowel threader.

Figure 21 is a global side view of a cutter blade.

Figure 22 is a detailed side view of the cutter blade of Figure 21.

Figure 23 is a detailed side view of the cutter blade of Figures 21 and 22.

Figure 24 is a top perspective view of one embodiment of an insertion tool of this invention.

Figure 25 is a side perspective view of the tool of Figure 24.

Figure 26 is a perspective view of a spacer engaging element of an insertion tool.

Figure 27 is a perspective view of a spacer engaging element of an insertion tool.

Figure 28 is a side elevational view of an insertion tool engaged to a spacer.

Figure 29 is a top perspective view of the view shown in Figure 28.

Figure 30 is an exploded side perspective view of a tool-spacer assembly according to this invention.

Figure 31 is a side perspective view of a tool-spacer assembly.

Figure 32 is a top perspective view of a fastener of this invention.

Figure 33 is a side elevational view of the fastener of Figure 32.

Figure 34 is a top elevational view of the fastener of Figures 32 and 33.

Figure 35 is a top elevational view of a spacer according to one specific embodiment of this invention.

Figure 36 is a side view of the spacer of Figure 35.

Figure 37 is a front perspective view of the spacer of Figure 35.

Figure 38 is a detail of a portion of the threaded surface of the spacer of Figure 35.

Figure 39 is a detail of one embodiment of the thread of one embodiment of the threaded dowel of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

This invention provides spacers having an open-mouthed chamber. These spacers are advantageous for maximum exposure of vertebral tissue to osteogenic material within the chamber and allow close placement of a pair of spacers within the intervertebral space. The design of these spacers conserve material without compromising biomechanical properties of the spacer. This is particularly advantageous when the material is bone because the invention preserves precious allograft. In fact, larger dowels and other shaped grafts can be obtained from smaller bones than was ever thought possible before the present invention. Likewise, smaller dowels having a pre-formed chamber may be efficiently obtained from larger bones.

Although any open-chambered spacer is contemplated, in one embodiment the spacers are obtained as an off-center transverse plug from the diaphysis of a long bone. This results in a dowel having an open-mouthed chamber. Because the long bone naturally includes the medullary canal, a pre-formed chamber is inherently contained within the dowel. When the plug is cut off-center in a certain way, the dowel includes an open-mouthed chamber. Surprisingly, the biomechanical properties of these dowels are not compromised by the absence of the missing chamber wall.

Referring now to Figures 4 and 5, one embodiment of an interbody fusion spacer of this invention is shown. The spacer 500 includes a body 505 with a tool engagement end 501 and an opposite insertion end 502. The body 505 includes a wall 506 defining a chamber 530 between the two ends 501, 502 and an opening 531 in communication with the chamber 530. Preferably, the insertion end 502 includes a solid protective wall 503 which is positionable to protect the spinal cord from escape or leakage of osteogenic material from the chamber 530 when the spacer is placed via an anterior approach.

As shown in Figure 4, the chamber 530 is open in that it also communicates with a further aperture such as a mouth or a channel. The aperture also communicates with the outer surface 510 of the spacer 500, preferably at the tool engagement end 501. The aperture can provide access to the chamber 530 after implantation or can facilitate insertion of the spacer 530 into the intervertebral space. Comparing Figure 4 with Figure 3, it is evident that the chamber 530 is open so that the body 505 and chamber 530 are substantially C-shaped as opposed to the defined chamber 330 of Figure 3. In some embodiments, including the one depicted in Figure 4, the aperture is a mouth 525 formed by a pair of facing and opposing arms 520, 521.

Bilateral placement of dowels 500 is preferred as shown in Figure 6. This configuration provides a substantial quantity of bone graft available for the fusion. The dual bilateral cortical dowels 500 result in a significant area of cortical bone for load bearing and long-term incorporation via creeping substitution, while giving substantial area for placement of osteogenic autogenous bone which will facilitate boney bridging across the disc space. The dual dowel placement with facing chambers 530 results in an elongated compartment 540 that can be filled with an osteogenic composition M. This provides for the placement

of a significant amount of osteogenic material as well as a large support area of cortical bone for load bearing.

The open spacers of this invention are advantageous because they complement the anatomy of the vertebrae V as shown in Figures 7-9. Figure 7 shows the variation in bone strength within the vertebral body V, with weaker bone W, disposed toward the center of the body B, and stronger bone S being disposed around the periphery, closest to the ring apophysis A. The open spacers of this invention are designed to accommodate spinal anatomy. As shown in Figure 8, two open spacers 500' can be implanted with the mouths 525' facing to the center of the intervertebral space. This capitalizes on the load bearing capability of the stronger peripheral bone S of the vertebral body V by placing the structural and load bearing portion of the spacer along the periphery of the body. At the same time, the osteogenic material M placed within the chambers is exposed to the more vascular center area W of the body.

In a preferred embodiment shown in Figure 10, the first arm 520' or the arm adjacent the tool engagement end 501', is truncated relative to the second arm 521'. This forms a channel 526 from the outer surface 510' to the chamber 530'. Preferably and as shown in Figure 10, the channel 526' is in communication with both the mouth 525' and the chamber 530' although it is contemplated that the channel 526 could be provided in a closed spacer having a chamber and an opening. In some embodiments, such as the spacer 550 depicted in Figure 11, the arms 580, 581 define concave faces or surfaces 582 and 583. The concave faces 582 and 583 are configured to receive a complementary driving tool.

The channel 526 of this invention provides important advantages. The channel 526, particularly when formed as a truncated arm 520' as shown in Figure 10, facilitates implantation with an insertion tool. Because the tool can be placed within the channel during implantation, two

spacers of this invention can be placed very closely together within the intervertebral space as shown in Figures 6 and 8. The tool need not extend beyond the outer surface of the spacer. The channel 526 also allows osteogenic material to be packed within the chamber and around the spacer after implantation. A further advantage of the channel is that, when it is formed in combination with the mouth of an open spacer, it allows the chamber of the spacer to be packed before implantation. The tool may be placed within the channel to prevent escape of the osteogenic material from the chamber during implantation. The channel 526 also provides access to the chamber 530' for packing after the spacer 500' is implanted into the disc space.

Referring now to Figure 12, in a preferred embodiment, the spacer is a dowel having a longitudinal axis A_l along a length L of the body 505. The open C-shaped chamber 530 is defined along a second axis A_p substantially perpendicular to the longitudinal axis A_l. The body 505 has an outer cross-section XS projected on a plane perpendicular to the longitudinal axis A_l that is substantially uniform along the length L of the body 505.

The spacers of this invention may be provided with surface features defined in the outer surface 510. Where the spacer is a bone dowel as described herein, the surface features can be machined into the cortical bone. Any desirable surface feature is contemplated. In one embodiment the outer surface 510 of the tool engaging end 501 defines a tool engaging or instrument attachment hole 515 as shown in Figures 4 and 12. In a preferred embodiment, the hole 515 is threaded but any suitable configuration is contemplated. It is sometimes preferable that this end 501 have a generally flat surface to accept the instrument for insertion of the dowel in the recipient.

In some embodiments, the spacer 500 includes an alignment score mark or groove 516 defined in the tool

engagement end 501. In Figure 12 the groove 516 is parallel to the axis A_p of the chamber 530 or perpendicular as shown in Figure 4. The score mark may be widened to form a driver slot for receiving an implantation tool. Alternatively, the end of the dowel may be machined to exhibit a projection instead of a slot. Such a protruding portion of bone may take a straight, flat-sided shape (essentially a mirror image of the slot shown), it may be an elliptical eminence, a bi-concave eminence, a square eminence, or any other protruding shape which provides sufficient end-cap or tool engaging end strength and drive purchase to allow transmission of insertional torque without breaking the dowel or the eminence. In other embodiments, a groove can be omitted to enhance the strength of the tool engaging end 501.

Other surface features can be defined along the length L of the spacer. The surface features can provide engaging surfaces to facilitate engagement with the vertebrae and prevent slippage of the spacer as is sometimes seen with a smooth graft. Referring now to Figure 13, the spacer 600 includes a groove or stop rib 632 inscribed along the circumference of the spacer. The rib 632 discourages backing out. In other preferred embodiments the outer surface 510' of the dowel 500" defines threads 542 as shown in Figure 14. The initial or starter thread 547 is adjacent the protective wall 503'. As shown more clearly in Figure 15, the threads 542 are preferably uniformly machined threads which include teeth 543 having a crest 544 between a leading flank 545 and an opposite trailing flank 546. Preferably the crest 544 of each tooth 543 is flat. In one specific embodiment, the crest 544 of each tooth 543 has a width w of between about 0.020 inches and about 0.030 inches. The threads 542 preferably define an angle α between the leading flank 545 and the trailing flank 546 of

adjacent ones of said teeth 543. The angle α is preferably between about 50 degrees and 70 degrees. Each tooth 543 preferably has a height h' which is about 0.030 inches and about 0.045 inches.

Machined surfaces, such as threads, provide several advantages that were previously only available with metal implants. Threads allow better control of spacer insertion than can be obtained with a smooth surface. This allows the surgeon to more accurately position the spacer and avoid over-insertion which is extremely important around the critical neurological and vascular structures of the spinal column. Threads and the like also provide increased surface area which facilitates the process of bone healing and creeping substitution for replacement of the donor bone material and fusion. These features also increase postoperative stability of the spacer by engaging the adjacent vertebral endplates and anchoring the spacer to prevent expulsion. Surface features also stabilize the bone-spacer interface and reduce micromotion to facilitate incorporation and fusion.

Various configurations of open-chambered spacers are contemplated by this invention. When the spacer is obtained from the diaphysis of a long bone, the shape of the dowel is determined by the location of the cut into the bone shaft. Referring now to Figure 16, by appropriately locating the plug that is cut, "C"-shaped dowels of varying "C"-shaped cavity depths and sidewall thicknesses are achievable. Figure 16A shows the plug that must be cut into the shaft to obtain a diaphysial cortical dowel 300 (see Figure 3) having a sidewall height H1 and a sidewall thickness T1. Figures 16B-16D depict the off-center cuts required to generate "C"-shaped dowels of this invention having different sidewall heights H2-H4 and sidewall thicknesses T2-T4. The sidewall thickness increases from 16A to 16D, even though the diameter of the dowel is unchanged.

Surprisingly, we have found that the open chambered spacers of this invention have biomechanical properties similar to a spacer having a defined or closed chamber. For example, the open-chambered bone dowel 500" of Figure 14 is no more susceptible to snapping or breakage during machining or implantation than the diaphysial cortical dowel 300 of Figure 3 having a full circular chamber. This strength is retained as long as the thickness T4 of the wall 506' at its narrowest aspect 570 is preferably no less than about 5 mm.

As any of these open-chambered spacers are implanted and begin to experience axial load, it is expected that the lower the sidewall height H, the greater the load carried by the dowel end 501, 502. However, where the sidewall height H is approximately the same as the dowel diameter D, the sidewall 506 may carry a greater share of this axial load.

In some embodiments, the wall 506 may include upper and lower flattened portions to stabilize the dowel by neutralizing any rotational torque that may be induced by pressure on the sidewall. This could be achieved by reducing the height H of the sidewall 505 and ends 501, 502 by filing or like means. These considerations may be less important for a threaded dowel than a non-threaded dowel as the threads tend to "bite" into the bone in which they are implanted, thereby preventing any rotation.

For cervical fusions, the dowel is preferably obtained from the fibula, radius, ulna or humerus. The dimensions of such dowels are typically between about 8-15mm in length or depth and about 10-14mm in diameter. For thoracic and lumbar fusions, the dowel is preferably obtained from the humerus, femur or tibia. The dimensions of such dowels are typically between about 10-30mm in length and about 14-20mm in diameter.

The chamber may be packed with any suitable osteogenic material. In a preferred embodiment, the osteogenic composition M has a length which is greater than the length

of the chamber 530 so that the osteogenic composition will contact the endplates of the adjacent vertebrae when the spacer 500 is implanted within the vertebrae. This provides better contact of the composition with the endplates to stimulate bone ingrowth.

Any suitable osteogenic material or composition is contemplated, including autograft, allograft, xenograft, demineralized bone, synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors. The terms osteogenic material or osteogenic composition used here means virtually any material that promotes bone growth or healing including autograft, allograft, xenograft, bone graft substitutes and natural, synthetic and recombinant proteins, hormones and the like.

Autograft can be harvested from locations such as the iliac crest using drills, gouges, curettes and trephines and other tools and methods which are well known to surgeons in this field. Preferably, autograft is harvested from the iliac crest with a minimally invasive donor surgery. The osteogenic material may also include bone reamed away by the surgeon while preparing the end plates for the spacer.

Advantageously, where autograft is chosen as the osteogenic material, only a very small amount of bone material is needed to pack the chamber. The autograft itself is not required to provide structural support as this is provided by the spacer. The donor surgery for such a small amount of bone is less invasive and better tolerated by the patient. There is usually little need for muscle dissection in obtaining such small amounts of bone. The present invention therefore eliminates or minimizes many of the disadvantages of employing autograft.

Natural and synthetic graft substitutes which replace the structure or function of bone are also contemplated for the osteogenic composition. Any such graft substitute is